DRAFT REVISION OF ISPM 18: Requirements for the use of irradiation as a phytosanitary measure (2014-007)

Status box

This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
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Steward history	2016-11 David OPATOWSKI (IL, Steward) 2020-10 Guy HALLMAN (US, Assistant Steward)
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Adoption

This standard was first adopted by the Fifth Session of the Commission on Phytosanitary Measures in April 2003. This first revision was adopted by the [XXXX] Session of the Commission on Phytosanitary Measures in [Month YYYY].

INTRODUCTION

Scope

This standard provides technical guidance on the application of ionizing radiation as a phytosanitary measure. This standard does not provide details on specific irradiation treatments, such as specific treatment schedules for specific regulated pests on specific commodities, or treatments used for the production of sterile organisms for pest control.

References

The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at www.ippc.int/core-activities/standards-setting/ispms.

APPPC (Asia and Pacific Plant Protection Commission). 2014. *Approval of irradiation facilities*. Regional Standard for Phytosanitary Measures (RSPM) 9. Bangkok, APPPC, FAO Regional Office for Asia and the Pacific. 20 pp.

IAEA (International Atomic Energy Agency). 2015. *Manual of good practice in food irradiation – Sanitary, phytosanitary and other applications*. Technical Reports Series No. 481. Vienna, IAEA. 85 pp.

ISO 14470:2011. *Food irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food.* Geneva, International Organization for Standardization. 20 pp.

ISO/ASTM 51261:2013. *Practice for calibration of routine dosimetry systems for radiation processing*, 2nd edn. United States of America, International Organization for Standardization and ASTM International. 18 pp.

Definitions

Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of requirements

This standard provides guidance on irradiation and its application as a phytosanitary measure to comply with phytosanitary import requirements.

The standard describes the roles and responsibilities of parties involved in the use of irradiation as a phytosanitary measure. It contains guidance for national plant protection organizations (NPPOs) on responsibilities for approving treatment facilities, and for monitoring and auditing treatment facilities and providers.

BACKGROUND

The purpose of this standard is to provide generic requirements for the application of ionizing radiation as a phytosanitary measure, specifically for those treatments adopted under ISPM 28 (*Phytosanitary treatments for regulated pests*).

ISPM 28 was adopted to harmonize effective phytosanitary treatments over a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may facilitate safe trade. ISPM 28 provides requirements for submission and evaluation of efficacy data and other relevant information on phytosanitary treatments. The annexes of ISPM 28 contain specific irradiation treatments that have been evaluated and adopted by the Commission on Phytosanitary Measures.

Irradiation is considered to be effective when the phytosanitary treatment dose of ionizing radiation (hereafter referred to as the "phytosanitary treatment dose") required by the treatment schedule is absorbed at the location in the process load that receives the lowest dose of radiation. Therefore, process control relies on identifying the minimum dose location for a specific loading configuration of a commodity and routinely delivering to this location a dose of ionizing radiation (a minimum dose) that is equal to or greater than the required phytosanitary treatment dose. The effectiveness of the treatment process also includes phytosanitary measures applied to prevent infestation or contamination after irradiation.

IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

Irradiation may be used to prevent the introduction and spread of regulated pests and hence may be beneficial to biodiversity. The use of irradiation as an alternative to methyl bromide fumigation provides an additional benefit to the environment by reducing methyl bromide emissions, which deplete the ozone layer.

REQUIREMENTS

1. Irradiation objective

The objective of using irradiation as a phytosanitary measure is to achieve, at a specified efficacy, certain pest responses such as:

- inability to develop successfully (e.g. non-emergence of adults);
- inability to reproduce (e.g. sterility);
- mortality (e.g. mortality of certain vectors of pests);
- inactivation; or
- devitalization of plants (e.g. seeds may germinate but seedlings do not grow; or tubers or bulbs do not sprout).

Where the required response is the inability of the pest to reproduce, a range of options may be specified. These may include:

- complete sterility in one or both sexes;
- oviposition or hatching without further development; or
- sterility of the F_1 generation.

2. Irradiation application

Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or caesium-137), electrons (up to 10 MeV) or X-rays (up to 7.5 MeV) generated from machine sources. The unit of measurement for absorbed dose is the gray (Gy).

The phytosanitary treatment dose is the minimum dose required to achieve the pest response at the specified efficacy. The treatment is dependent upon the understanding of dose distribution within the loading configuration and consistent presentation of the process load to the ionizing radiation. Factors that may alter the effectiveness of the treatment may include inconsistent loading configurations and variable levels of oxygen (O_2).

To ensure that the phytosanitary treatment dose has been attained throughout the process load, treatment procedures should ensure that the minimum absorbed dose (D_{min}) is equal to or greater than the required phytosanitary treatment dose. The intended use of the commodity should be considered. For example, although appropriate for foods and agricultural products for processing or consumption, irradiation may not be appropriate for plants for planting, as it may devitalize them, and maximum absorbed doses may need to be considered as prescribed by food safety authorities.

It is rare that mortality is technically justified as the required response to irradiation. It is therefore possible for live, non-viable target pests to be found in correctly treated commodities. This does not imply a failure of the treatment. It does mean, however, that it is essential for the treatment to be applied correctly to ensure that any target pests that are still alive are unable to complete development or otherwise reproduce. In addition, it is preferable that such pests are unable to escape into the environment unless they can be distinguished from non-irradiated pests.

Irradiation may be applied:

- as an integral part of packing operations;
- to bulk unpackaged commodities; or
- to packaged commodities.

Irradiation may take place in the country of origin. When it is operationally feasible to prevent the escape of any pests during transport of the untreated commodity, treatment may alternatively be conducted at:

- the point of entry;
- a designated location in a third country; ora designated location within the country of final destination.

Treated commodities should be certified and released only after dosimetry measurements show that no absorbed doses were less than the required phytosanitary treatment dose and therefore that the dose requirement has been met throughout the process load.

Depending on the pest risk to be managed, the tolerance of the commodity to treatment, and the availability of other pest risk management options, irradiation may be used either as a single phytosanitary measure or combined with other measures as part of a systems approach (see ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*)).

3. Dosimetry

Irradiation does not deliver a uniform dose throughout a process load but a continuum of doses. The dose range may increase as the size or density of the treated material increases. Therefore, it is important that an accurate measurement of the absorbed dose in a process load can be readily determined to ensure that the required phytosanitary treatment dose has been reached throughout the load.

Dosimetry provides assurance that D_{min} is equal to or greater than the required phytosanitary treatment dose and therefore that the dose requirement has been met throughout the process load. Properly designed systems for treatment delivery and protection against infestation and contamination, together with continual checking and regular monitoring of those systems, provide assurance that treatments are properly conducted. Dosimetry is highly specialized; NPPOs unfamiliar with irradiation should therefore collaborate with technical experts from their national nuclear agencies when approving facilities to be used for irradiating commodities for phytosanitary purposes.

3.1 Dosimetry systems

A dosimetry system consists of dosimeters, instruments that read dosimeters, and associated procedures and standards. A dosimeter is a device with a reproducible response to irradiation that can be used to measure the absorbed dose. The dosimeter responds to the radiation and the response is measured by instruments to calculate the amount of ionizing radiation that the process load has absorbed (expressed as absorbed dose).

The selection and use of specific dosimetry systems should be appropriate for both the dose range and the type of radiation. It should take into account the influence of factors such as dose rates, the level of uncertainty deemed to be acceptable and the required spatial resolution. Examples of dosimetry systems that can be used for gamma ray, electron beam and X-ray facilities can be found in ISO/ASTM 51261:2013.

3.2 Dose mapping

Dose mapping is performed by placing dosimeters throughout the process load, irradiating the process load and reading the dosimeter values. Further information on the practices used for electron beams and X-rays are described in ISO 14470:2011 and ISO/ASTM 51261:2013.

The objectives of dose mapping are:

- to determine the dose distribution throughout the process load and in particular where D_{min} and D_{max} are found;
- to demonstrate that the required phytosanitary treatment dose can be attained for the process load (i.e. D_{min} can be equal to or greater than the required phytosanitary treatment dose);
- to establish the process parameters that will lead to doses within the required range;
- to assess the variability of the particular process; and
- to establish how routine dose measurements will be made.

The dose distribution in a process load is specific to the irradiator, the path and speed that the commodity takes through the irradiator, the load configuration and the characteristics of the commodity. If any of these factors change, dose mapping should be repeated, as such changes affect dose distribution.

3.3 Routine dosimetry

Accurate measurements of absorbed dose in a process load are critical for determining the effectiveness of the treatment. They are part of the quality control of the treatment and of the validation process. The required number, location and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.

When the position of D_{min} or D_{max} is inside the process load and it is not practical to place dosimeters there routinely, a dosimeter may be placed in a reference location on the surface of the process load or on the irradiation container in a location that is readily accessible and easily reproducible for the operator (see Appendix 1). For a given loading configuration, a given path through the irradiator or given machine settings, the relationship between the dose measured at the reference location (D_{ref}) and D_{min} and D_{max} is arithmetic and constant. The coefficient representing this relationship should be established by dose mapping and may then be used to calculate D_{min} and D_{max} from D_{ref} during routine dosimetry.

4. Validation

Validation encompasses a series of checks designed to verify that a treatment facility meets its installation requirements (installation qualification), operates to its design specification (operational qualification) and will consistently deliver the required dose to a given process load within predetermined tolerances (performance qualification).

Installation qualification and operational qualification validate the irradiator and may be performed by the treatment provider with the technology suppliers. National plant protection organizations are typically not involved with installation- or operational-qualification activities, but the treatment provider should inform the NPPO if major changes have been made to the facility that would require dose mapping to be repeated (e.g. replenishment of gamma sources or major changes to conveyor-belt systems or speeds).

The way in which the commodity is loaded and irradiated is based on the results of the performance qualification. Therefore, the NPPO should review the performance-qualification activities that are undertaken with the actual commodity and loading configuration (e.g. full pallet or half pallet). The objective of performance qualification is to demonstrate that the equipment, as installed and properly operated, consistently performs as expected and that the treatment schedule can be met. Dose mapping of the actual process load to define the loading configuration is a key activity to ensure that the required phytosanitary treatment dose is achieved.

5. Adequate systems for treatment facilities

Confidence in the adequacy of irradiation as a phytosanitary measure is primarily based on assurance that the treatment schedule is effective against the target pests under specific conditions and the treatment has been properly applied. Systems for treatment delivery in the facilities should be designed, used and monitored to ensure that treatments are properly conducted.

The NPPO of the country in which the treatment facility is located is responsible for ensuring that the facility system requirements are met.

5.1 Approval of treatment facilities and authorization of treatment providers

Treatment facilities should be approved by the NPPO of the country in which the facility is located before phytosanitary treatments are applied there, with such approval thereby providing authorization to the treatment provider responsible for the facility to conduct treatments according to agreed procedures. This approval should be subsequent to authorization from competent authorities for safety (e.g. radiation safety authority, nuclear regulatory authority) where appropriate and be based on a set of criteria that include both criteria common to all irradiation facilities and those that are specific to the site and commodity (see Annex 1). Guidance on authorizing entities to perform phytosanitary actions can be found in ISPM 45 (*Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions*).

Evaluation of irradiation facilities for re-approval should be carried out by the NPPO on a regular basis at appropriate intervals.

5.2 Prevention of infestation and contamination after treatment

The consignment owner is responsible for prevention of infestation and contamination after irradiation and may cooperate with the treatment provider on how to achieve this. At the treatment facility, the necessary measures should be implemented to prevent possible infestation or contamination of the commodity after treatment. The following measures may be required:

- keeping the commodity in a pest free enclosure under conditions that protect it from infestation and contamination;
- packing the commodity immediately after irradiation;
- segregating and identifying irradiated commodities; and
- dispatching the commodity as soon as possible after irradiation.

The use of pest-proof packaging before irradiation may help to prevent possible infestation or contamination after irradiation. It may also prevent the accidental escape of the target pests before treatment if irradiation is applied at the destination.

5.3 Labelling

The treatment provider is responsible for labelling commodities with treatment lot numbers or other identifying features allowing trace-back for non-compliant consignments. The labels should be easily identifiable and placed in visible locations.

5.4 Monitoring and auditing

The NPPO of the country in which the irradiation is conducted should monitor and audit treatment facilities and providers in accordance with ISPM 47 (*Audit in the phytosanitary context*). The NPPO should maintain an audit schedule and ensure that such audits are conducted by appropriately trained personnel. Continuous supervision of irradiation by the NPPO should not be necessary, provided treatment procedures are properly designed by the treatment provider and can be verified to ensure a high degree of system integrity for the facility, process and commodity in question. The monitoring and auditing should be sufficient to detect and correct deficiencies promptly.

Treatment providers should meet monitoring and auditing requirements set by the NPPO. These requirements may include:

- access for the NPPO to conduct audits, including unannounced visits;
- a system to maintain and archive treatment records and provide the NPPO with access to these; and
- corrective action to be taken in the event of nonconformity.

The NPPO of the importing country may establish approval and audit procedures with the NPPO of the exporting country to verify conformity with requirements.

6. Documentation

The NPPO of the country in which the irradiation is conducted is responsible for ensuring that treatment providers document all operational procedures and keep appropriate records, such as raw data on dosimetry readings recorded during treatments. Accurate record-keeping is essential to enable auditing and trace-back.

6.1 Documentation of procedures

Procedures should be documented by treatment providers to ensure that commodities are consistently treated as required. Process controls and operational parameters should be established to provide the details necessary for the specific approval of a treatment facility. Calibration and quality control

procedures should be documented by the treatment provider. The documented procedures should include the following:

- commodity-handling procedures before, during and after irradiation;
- orientation and loading configuration of the commodity during irradiation;
- critical process parameters and the means for measuring and recording them;
- dosimetry and calibration of the dosimetry system;
- contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes;
- procedures for handling rejected lots;
- labelling, record-keeping and documentation requirements; and
- training of personnel.

6.2 Record-keeping

The treatment provider should keep appropriate records for each treatment application. These records should be made available to the NPPO of the country in which the treatment facility is located for auditing and verification purposes or when a trace-back is necessary.

Appropriate treatment records for irradiation as a phytosanitary measure should be retained by the treatment provider for at least one year to enable the trace-back of treated lots. Information that may be required to be recorded includes:

- identification of facility and responsible parties;
- commodity treated;
- target regulated pest;
- treatment objective (i.e. required response);
- owner, packer, grower and place of production of the commodity;
- lot size and volume, including number of articles or packages;
- identifying markings or characteristics;
- orientation and loading configuration of the commodity during irradiation;
- absorbed doses (required doses and measured doses), dosimetry calibration and dose mapping records;
- date of treatment; and
- any observed deviation from the treatment schedule and, where appropriate, subsequent actions taken.

6.3 Documentation by the NPPO

All NPPO procedures should be appropriately documented. Records, including those of monitoring inspections made and phytosanitary certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available upon request as described in ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*).

7. Inspection

Inspection should be carried out by the NPPO of the exporting country and inspection at import may be carried out by the NPPO of the importing country to determine compliance with phytosanitary import requirements.

Live target pests may be found during inspection after irradiation, but this should not result in the refusal to issue a phytosanitary certificate. Where mortality is not the required response, it is likely that live target pests may persist in the treated consignment; in such cases, phytosanitary certification should be

based on confirmation from the validation programme that the required minimum dose is administered and the required response is achieved for the specific treatment conditions concerned (see section 2).

8. Responsibilities

The NPPO of the country in which the irradiation is conducted is responsible for the evaluation, approval and auditing of the application of irradiation as a phytosanitary measure.

To the extent necessary, the NPPO should cooperate with other national regulatory agencies concerned with the development, approval and safety of irradiation, including the training and certification of personnel conducting the treatment and the approval of treatment facilities. The respective responsibilities of the NPPO and the other regulatory agencies should be identified to avoid requirements that are overlapping, conflicting, inconsistent or unjustified.

The treatment provider is responsible for implementing the treatment in accordance with the NPPO requirements, for documenting procedures, for keeping the treatment records, and for making these documents and records available for auditing and verification purposes.

This annex is a prescriptive part of the standard.

ANNEX 1: Checklist for irradiation facility approval or auditing

This checklist may be used by an NPPO as part of an approval or auditing process of an irradiation facility.

Criteria	Yes	No	Comments
1. Premises			
The facility meets the NPPO phytosanitary requirements, and the NPPO has access to the facility and appropriate records as necessary to validate phytosanitary treatments.			
Facility buildings are designed and built to be suitable in size, materials and placement of equipment to facilitate proper maintenance and operations for the lots to be treated.			
Appropriate means, integral to the facility design, are available to maintain non-irradiated lots separate from irradiated lots.			
Buildings and equipment are maintained in a sanitary condition and in repair sufficient to prevent infestation or contamination of the lots being treated.			
Effective measures are in place to protect against the infestation or contamination of consignments or lots being stored or processed.			
Adequate measures are in place to handle breakages, spills or other damage to lots.			
Adequate systems are in place to dispose of lots that are improperly treated or unsuitable for treatment.			
Adequate systems are in place to control non-compliant lots.			
2. Personnel			
The facility is adequately staffed with trained personnel.			
Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes.			
3. Commodity handling, storage and segregation			

Criteria	Yes	No	Comments
Commodities are examined upon receipt to ensure that they are suitable for irradiation. Commodities are handled in an environment that does not increase the risk of dangerous physical, chemical or biological contaminants. Commodities are appropriately stored and adequately identified. Procedures, equipment and structures are in place to ensure the segregation of irradiated and non-irradiated lots, including physical separation between incoming and outgoing holding areas.			
4. Irradiation			
The facility is suitably designed and equipped to allow required treatments to be conducted in conformity with a treatment schedule. A process control system is in place providing criteria to assess irradiation effectiveness. Proper process parameters are established for each type of commodity to be treated. Written procedures have been submitted to the NPPO and are well known to appropriate facility personnel. The absorbed dose delivered to each type of commodity is verified by proper dosimetric-measurement practices using calibrated dosimetry, and dosimetry records are kept and made available to the NPPO as needed.			
5. Packaging and labelling			
Each commodity is packaged using materials suitable for the commodity and process. Irradiated lots are adequately identified or labelled and adequately documented.			
6. Documentation			
All records about each lot irradiated are retained at the facility for the period of time specified by relevant authorities (at least one year) and are available for inspection by the NPPO as needed.			

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 1: Example of a dosimeter in a reference location

In Figure 1, the coefficients (R_{min} and R_{max}) representing the relationship between the minimum (D_{min}) and maximum (D_{max}) absorbed doses and the absorbed dose in the reference location (D_{ref}) have been calculated as 0.8 and 1.4, respectively. The calculations are as follows:

Measured values:
D_{max} = 4.2 kGy
D_{min} = 2.4 kGy
D_{ref} = 3.0 kGy

Therefore:
$R_{min} = D_{min}/D_{ref}$ = 2.4 kGy/3.0 kGy = 0.8
$R_{max} = D_{max}/D_{ref}$ = 4.2 kGy/3.0 kGy = 1.4

Thus, if the target dose range is D_{min} = 2.0 kGy and D_{max} = 5.0 kGy, one can estimate the routine values for D_{ref} to be:

$D_{ref} = D_{min}/R_{min}$ = 2.0 kGy/0.8 = 2.5 kGy at a minimum
$D_{ref} = D_{max}/R_{max}$ = 5.0 kGy/1.4 = 3.57 kGy at a maximum.

For further examples, please refer to IAEA (2015).

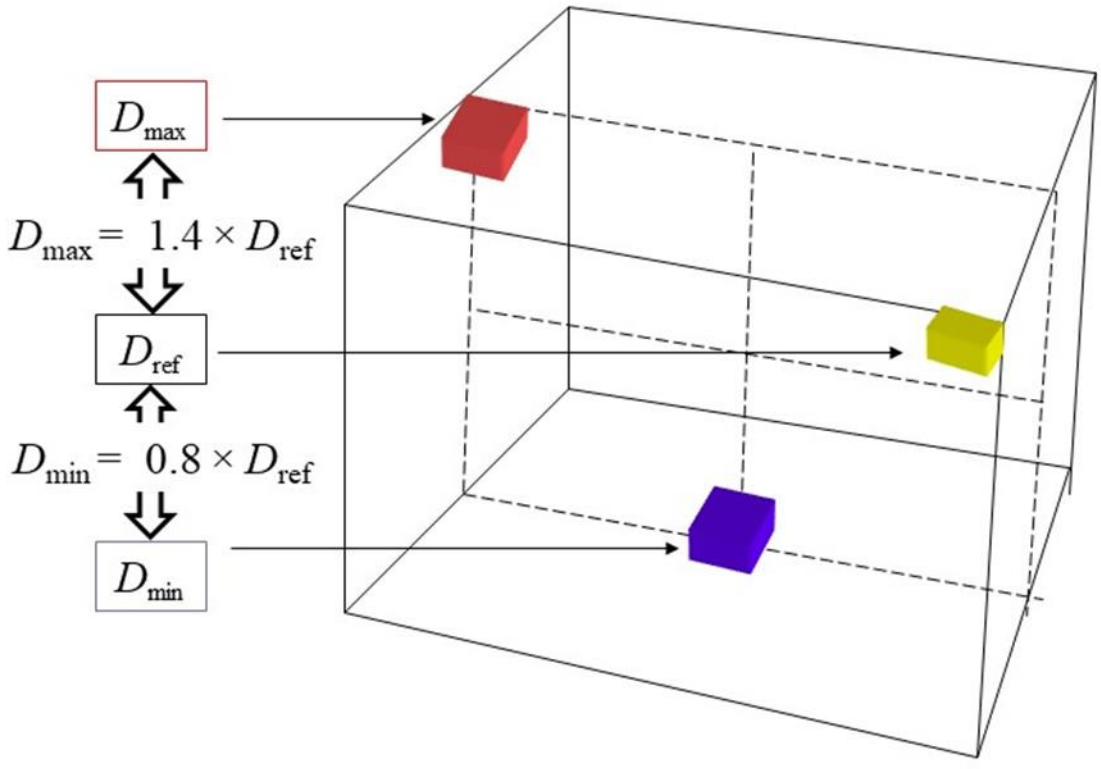

Figure 1. Example of relationship between minimum and maximum absorbed doses and the absorbed dose in the reference position. Blue box, position of minimum absorbed dose (D_{min}); red box, position of maximum absorbed dose (D_{max}); yellow box, position of dosimeter in the reference location (absorbed dose measured is D_{ref}).

Source: IAEA (International Atomic Energy Agency). 2015. *Manual of good practice in food irradiation – Sanitary, phytosanitary and other applications.* Technical Reports Series No. 481. Vienna, IAEA. 85 pp. Reproduced with permission from the IAEA.